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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,863	10/30/2003	David E. Clapham	110313.135US3	1595
23483	7590	11/15/2011		
WILMERHALE/BOSTON 60 STATE STREET BOSTON, MA 02109			EXAMINER WEGERT, SANDRA L	
			ART UNIT 1646	PAPER NUMBER
			NOTIFICATION DATE 11/15/2011	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/697,863	<b>Applicant(s)</b> CLAPHAM ET AL.	
	<b>Examiner</b> SANDRA WEGERT	<b>Art Unit</b> 1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 112, 113 and 115-136 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☒ Claim(s) 135 is/are allowed.
- 7) ☒ Claim(s) 112 and 136 is/are rejected.
- 8) ☒ Claim(s) 113, 115-134 is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/12/11</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Status of Application, Amendments, and/or Claims***

With the Supplemental Amendment of 8 August 2011, claims 1-111 and 114 are cancelled. Claims 112, 113, 115, 116, 119, 121 and 123-132 are amended. Claims 135 and 136 are new.

Claims 112, 113 and 115-132 are under examination in the instant Office Action.

### **Withdrawn Objections/Rejections**

#### ***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

The rejection of claims 3-6 under 35 U.S.C. § 112, second paragraph, as being indefinite, are withdrawn based on the claim amendments which cancelled the claims (12 May 2011). In addition, newly-submitted claims do not recite the indefinite claim language described in the office action of 12 November 2010.

#### ***35 U.S.C. § 101-Product of Nature/Gene Therapy***

The following is a quotation of 35 U.S.C. 101:

**Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.**

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The rejection of claims 21-25, under 35 U.S.C. 101, for non-statutory subject matter (A cell" and "A" nucleic acid) is *withdrawn*. Applicants cancelled claims 21-25 and amended new claims to recite "the cell" and "the nucleic acid" (10 August 2011).

***Claim Rejections - 35 USC § 112, first paragraph - Scope of enablement.***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

**The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

The rejection of claims 3-6 and 8-25 under 35 U.S.C. 112, first paragraph, for reciting "allelic variants," "functional equivalents," or fragments "consisting essentially of nucleic acids" that hybridize to SEQ ID NO: 1 at moderate stringency, is *withdrawn*. Applicants cancelled claims 3-6 and 8-25 (12 May 2011). Newly submitted claims to not recite these elements (10 August 2011).

**Maintained/New Objections and/or Rejections**

**Informalities-**

***Sequence Rules***

The instant application is not fully in compliance with the sequence rules, 37 CFR 1.821-1.825, especially 1.821, part (c), because each disclosure of a sequence embraced by the definitions set forth in the rules must be accompanied by the required reference to a sequence

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identifier (i.e., SEQ ID NO:). This occurs in Figure 1A and 1C. Each sequence in a Figure must be identified by a SEQ ID NO, either in the Figure itself or in the Brief Description.

Appropriate correction is required.

Claims 113 and 115-134 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Claim Rejections- 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 112 and 136 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillier, et al (1997b, Accession No. AA416577.1; hereinafter, "Hillier"). Hillier discloses residues 1959 to 2343 of instant SEQ ID NO: 1 (see the alignment in Appendix A of the Office action of 12 November 2010). This covers residues 2057 to 2343 of instant SEQ ID NO: 1, which encodes SEQ ID NO: 2. The sequence disclosed by Hillier would be expected to hybridize to SEQ ID NO: 1, making it complementary, even though it is shorter than instant SEQ ID NO: 1. Amending claims 112 and 136 to recite that the complementary nucleotide sequence is

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"completely" complementary or "fully" complementary, or words to that effect, would obviate this rejection.

Applicants argue (12 May 2011, p. 6):

**"Hillier 1997b only discloses residues 1959 to 2343 of instant SEQ ID NO: 1. Therefore, Hillier 1997b does not anticipate claim 112 nor any of the instantly-claimed nucleic acids. In view of the new claims, Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) be reconsidered and withdrawn."**

Applicant's arguments have been fully considered but they are not persuasive. The examiner agrees that part (a) of both claim 112 and claim 136 embraces the full-length nucleic acid encoding SEQ ID NO: 2 (SEQ ID NO: 1). However, part (b) of both claims embraces a probe of indefinite length, even one that is much shorter than the reference nucleic acid. All that is required of the nucleic acid in part (b) is that it binds SEQ ID NO: 1 in a complementary fashion; the claims says nothing about its required length. Hence, Hillier anticipates claims 112 and 136 because the reference discloses a complementary nucleic acid that is 384 residues in length.

**Conclusion:** Claims 112 and 136 are rejected for the reasons recited above. Claims 113 and 115-134 are objected to. Claim 135 is allowable.

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### **Advisory information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Nickol, can be reached at (571) 272-0835.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you

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would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

/SLW/

31 October 2011

/Gary B. Nickol /

Supervisory Patent Examiner, Art Unit 1645